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No. 06-1582

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IN THE

Supreme Court of the United States

PFIZER INC.,

Petitioner,

v.

APOTEX, INC. (formerly known as TorPharm, Inc.),

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

SUPPLEMENTAL BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

DOUGLAS R. COLE
JONES DAY
325 John H. McConnell Blvd., Suite 600
Columbus, OH 43216
(614) 469-3939

RICHARD G. GRECO
MILTON SHERMAN
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
(212) 836-8000

GLEN D. NAGER
(Counsel of Record)
GREGORY A. CASTANIAS
MICHAEL S. FRIED
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939
Counsel for Petitioner

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

In its petition for certiorari (filed May 30, 2007), Pfizer has sought review of the Federal Circuit's judgment declaring U.S. Patent No. 4,879,303 ("the '303 patent") invalid on obviousness grounds. The '303 patent covers amlodipine besylate, the active ingredient in Norvasc®, which is the world's largest selling brand-name drug for treating hypertension.

In addition to filing the petition for certiorari, Pfizer also asked the Court to recall and stay the Federal Circuit's mandate, and to expedite consideration of the petition. On June 6, 2007, Justice Stevens denied the application to recall and stay the mandate, and on June 11, 2007, the Court denied the motion to expedite.

On June 14, 2007, in response to these decisions, Pfizer filed a letter with the Food and Drug Administration seeking to have the '303 patent delisted from the FDA's Approved Drug Products List with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book"). Pfizer was compelled to submit this letter because, in view of the Federal Circuit's ruling, and this Court's recent decisions on the above-referenced motions, the '303 patent could not, under the present state of facts, "reasonably be asserted" against any company manufacturing a generic version of amlodipine besylate. *See* 21 U.S.C. § 355(b)(1)(G). A copy of that letter is reproduced in the Appendix to this Supplemental Brief (at 1-2).

The purpose of this Supplemental Brief is to apprise the Court of this delisting letter, and to explain that the letter does not interfere with the Court's consideration of Pfizer's petition for certiorari. In particular, the letter does not moot further consideration of that petition.

As the petition explains, the '303 patent expired on March 25, 2007. *See* Pet. at 6. Under the Better Pharmaceuticals for Children Act, however, Pfizer was entitled to an

additional six-month period of exclusivity, the so-called pediatric exclusivity period,* during which the FDA would not approve Abbreviated New Drug Applications (ANDAs) for generic equivalents to Norvasc. *Id.* To be sure, now that Pfizer has requested the delisting of its patent, the '303 patent does not—under the present posture of this case—block FDA approval of competing manufacturers' ANDAs for generic amlodipine besylate. If the Court decides Pfizer's petition before September 25, 2007 (the end of the statutory six-month exclusivity period) and vacates the decision below as Pfizer has requested, then there would be a reasonable basis for asserting the '303 patent, and Pfizer can seek to have the '303 patent relisted. Such a relisting would reinstate the pediatric exclusivity period, thereby returning to Pfizer at least some benefit from the statutory exclusivity to which it was entitled. Accordingly, the delisting letter does not moot this case.

If, on the other hand, the Court does not rule on the petition until after September 25, 2007, then the case *will* become moot as a result of the expiration of the pediatric exclusivity period itself. *See* Pet. at 16-19. At that point, the '303 patent would have no more exclusionary force, as both the patent and its associated pediatric exclusivity period would have expired—meaning that there would no longer be a live controversy. In that circumstance, as described more fully in the petition, *see id.*, under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950) and *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994), the Court should vacate all of the decisions below, as

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* The "pediatric exclusivity period" is so named because it provides for an additional six months of market exclusivity as an incentive for new drug manufacturers to conduct pediatric studies requested by the Food and Drug Administration. *See* 21 U.S.C. § 355a(b). The market exclusivity extends to all uses of the drug, whether in children or adults.

the case would have become moot due to events beyond Pfizer's control.

Respectfully submitted,

DOUGLAS R. COLE
JONES DAY
325 John H. McConnell Blvd., Suite 600
Columbus, OH 43216
(614) 469-3939

RICHARD G. GRECO
MILTON SHERMAN
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
(212) 836-8000

GLEN D. NAGER
(Counsel of Record)
GREGORY A. CASTANIAS
MICHAEL S. FRIED
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939
Counsel for Petitioner

June 21, 2007

APPENDIX

June 14, 2007

VIA FEDERAL EXPRESS
Ms. Mary Ann Holovac
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs/HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

PATENT INFORMATION

Re: NDAs 19-787 and 21-540

Dear Ms. Holovac:

Pfizer is hereby notifying FDA that Patent No. 4,879,303 no longer meets the legal criteria for listing in the "Orange Book." Thus, please remove (or "de-list") the '303 patent from the Orange Book listings for NDAs 19-787 (Norvasc®) and 21-540 (Caduet®).

On March 22, 2007, the Court of Appeals for the Federal Circuit (CAFC) held that the claims of the '303 patent covering the besylate salt of amlodipine were invalid for obviousness. The CAFC denied Pfizer's motion for rehearing *en banc* and issued its mandate on May 21. Pfizer immediately sought certiorari from the U.S. Supreme Court, and moved (i) to have the mandate recalled and stayed, and (ii) to have the consideration of its petition expedited. On

June 6, the Supreme Court denied Pfizer's motion to recall the CAFC's mandate and stay the case while Pfizer's petition for certiorari was pending. Further, on June 11 the Supreme Court denied Pfizer's motion to expedite consideration of its petition for writ of certiorari.

Pfizer will continue to seek the Supreme Court's review of the Federal Circuit's decision. Nonetheless, in light of the Federal Circuit's mandate and the Supreme Court's decisions with respect to Pfizer's motions, the '303 patent no longer meets the patent listing criteria set forth in 21 USC 355(b)(1), because the patent now cannot "reasonably be asserted" against an unlicensed manufacturer of amlodipine besylate. Thus, Pfizer is compelled to request that the '303 patent be removed from the Orange Book.

Thank you very much for your attention to this matter.

Very truly yours,

/s/ Bruce A. Pokras

Bruce A. Pokras

cc: U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266